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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,578	10/09/2003	Muhammed Majeed		2577

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EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/605,578

Applicant(s)

MAJEED ET AL.

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-10 are pending in the application and were examined on the merits.

Claim Objections

Claims 2 and 3 are objected to because of the following informalities:

Claim 2 states 'modified with solvent selected...' which should properly read 'modified with a solvent'.

Claim 3 recites several selenium compounds. These selenium compounds; i.e., selenoamino acids, should not be capitalized.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps leading to an enrichment concentrate containing selenium compounds. There are no steps in this claim. Because there are no steps in this claim, claim 1 was examined on the merits as if it possessed the limitations of claim 2.

Claim 1 recites 'specific organic selenium compounds'. This phrase is indefinite because the metes and bounds of this language cannot be clearly delineated and one of ordinary skill in the art would not know if he/she were in possession of such compounds. Which organic selenium compounds is the claim referring to?

Claim 2 recites 'with [sic] solvent selected from alcohols, ethyl acetate, water singly or in combination in various proportions...' This statement is indefinite for several reasons. First, it is unclear what is among the constituents to be selected. Does this statement mean that a selection is made from alcohols, ethyl acetate, water or a combination thereof? If this is the case, the claim does not clearly convey this limitation because the phrase 'in combination' is not clearly delineated. In combination with what

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element(s)? Further, does 'singly' refer to the water, or to all of the other constituents; i.e., alcohols, ethyl acetate? Further, the term 'various' is indefinite. The ordinary artisan would not be able to ascertain what the invention is actually limited to, and therefore this term is ambiguous.

Claim 2 further recites 'other procedures including but not limited to preparative high performance...'. First, the term 'other procedures' is indefinite because it is not clear what procedures Applicant intends to claim. Further, 'including but not limited to' is indefinite; is the step of high performance liquid chromatography a limitation of the claim? It is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 3 recites the term 'such as' on lines 2 and 4. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claim 3 also recites 'related compounds'. This term is indefinite because there is no clear definition of 'related compounds' in the Instant specification. Although a compound may be 'related' to the claimed compounds; i.e., L-selenomethionine, does not mean that it is present in an extract of garlic. Further, claim 3 recites 'the organic compounds of claim 1'. Because claim 1 is a method claim, claim 3 should refer to the method of claim 1; i.e., "The method of claim 1, wherein said compounds include...". Correction is necessary.

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Claim 4 states 'in the form of organic selenium compounds of claim 1'. As stated *supra*, claim 1 is found indefinite in part because the terms 'specific organic selenium compounds' is indefinite (see *supra*). Because it is not known what compounds claim 1 is referring to, claim 4 is also indefinite in that 'organic selenium compounds of claim 1' cannot be delineated. This claim is further confusing because it refers to the compounds of claim 1, wherein claim 1 is a method claim. Is Applicant intending to limit claim 1 or to create a new independent claim? It is unclear if Applicants intend for this claim to possess the limitations of claim 1 (which again, the Examiner has included the limitations of claim 2 since claim 1 does not include any method steps).

Claims 5-10 all refer to the 'composition of claim 4', while claim 4 is a method claim, therefore creating confusion. Clarification is necessary.

It is noted that because claim 1 is a method claim, all of the claims were searched on the merits as if they were drawn to a method for preparing a composition. To reiterate, the claims were searched with regard to the prior art as if claim 2 were present in claim 1. A search on the merits for all limitations of the claims was difficult because of the ambiguity of the claim language. However, it is noted that a method for extracting the selenium compounds as listed in claim 3, via supercritical carbon dioxide extraction followed by chromatography methods is not found in the art.

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The closest prior art of record are McSheehy et al. (2000) and Kotreibai et al. (1999). McSheehy et al. (2000) examined the selenium compounds in garlic via HPLC, plasma mass spec and tandem spec (see Abstract). McSheehy et al. found that γ -glutamyl-Se-methylselenocysteine made up 78% of the selenium present in naturally occurring garlic (p. 6). McSheehy et al. did not disclose or suggest isolation of these compounds via supercritical carbon dioxide extraction. Kotreibai et al. (1999) showed that selenium-enriched garlic contained Se compounds such as selenomethionine, γ -glutamyl-Se-methylselenocysteine (p. 75). However, Kotreibai et al. did not disclose, or suggest isolation of these compounds via supercritical carbon dioxide extraction.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

10/14/04

A handwritten signature in cursive script, appearing to read "Patricia Leith", with a long horizontal flourish extending to the right.